

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: Storer *et al.* Confirmation No.: 2201
Serial No.: 10/608,907 Art Unit: 1623
Filed: June 27, 2003 Examiner: T. McIntosh III
For: MODIFIED 2' AND 3' NUCLEOSIDE Attorney Docket No: 11874-055-999
PRODRUGS FOR TREATING (CAM: 417451-999055)
FLAVIVIRIDAE INFECTIONS IDX 1018

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

Mail Stop Petition
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Patentees respectfully request reconsideration of the Determination of Patent Term Adjustment under 35 U.S.C. §154(b) ("Determination") stated on the Issue Notification of October 7, 2009 in connection with the above-captioned application. It is alleged in the Determination that the patent term adjustment is 918 days. Applicants respectfully disagree. As set forth below, the correct patent term adjustment is 1,433 days.

A. Statement of the Facts Under 37 C.F.R. § 1.705(b)(2)

Pursuant to 37 C.F.R. § 1.702, Applicants submit the following statement of facts in support of this Application for Patent Term Adjustment.

The patent term adjustment due to Office delays is the sum of Office delays under 35 U.S.C. § 154(b)(1)(A) and 35 U.S.C. § 154(b)(1)(B), minus Applicants' delay under 37 C.F.R. § 1.704. The details of this calculation are provided below.

1. Patent Office Delays Under 35 U.S.C. §154(b)(1)(A)

As described below, the total Office delay under 35 U.S.C. § 154(b)(1)(A) is 543 days, which is consistent with the calculations provided in the Patent Term Adjustment History

obtained from the Patent Application Information Retrieval (“PAIR”) of the United States Patent and Trademark Office website.

The filing date of the instant patent is June 27, 2003. Thus, a first action was due August 27, 2004, *i.e.*, fourteen months after the date of filing. *See* 37 C.F.R. §1.703(a)(1) (patent term adjustment is equal to the number of days “in the period beginning on the day after the date that is fourteen months after the date on which the application was filed...and ending on the date of mailing of...an action under 35 U.S.C. §132....”); 35 U.S.C. 154(b)(1)(A)(i). A Restriction Requirement was not mailed until January 11, 2006. Thus, the period of Office delay for failure to issue an action within 14 months is 502 days.

A Response after non-final Office Action was filed August 20, 2007. Thus, an Office Action under 35 U.S.C. § 132, or a Notice of Allowance under 35 U.S.C. § 151, was due December 20, 2007. *See* 37 C.F.R. § 1.703(a)(2) (patent term adjustment is equal to the number of days “in the period beginning on the day after the date that is four months after the date on which a reply under 37 C.F.R. 1.111 was filed and ending on the date of mailing of...an action under 35 U.S.C. 132....”); 35 U.S.C. § 154(b)(1)(A)(ii). A non-final Office Action was mailed January 28, 2008, an Office delay of 39 days.

A Response after non-final Office Action was subsequently filed July 24, 2008. Thus, an Office Action under 35 U.S.C. § 132, or a Notice of Allowance under 35 U.S.C. § 151, was due November 24, 2008. *See* 37 C.F.R. § 1.703(a)(2). A non-final Office Action was mailed November 26, 2008, an Office delay of 2 days.

Thus, the total PTO delay under 35 U.S.C. § 154(b)(1)(A) is $502 + 39 + 2$ days = 543 days.

2. Patent Office Delays Under 35 U.S.C. §154(b)(1)(B)

“[I]f the issue of an original patent is delayed due to the failure of the United States Patent and Trademark Office to issue a patent within 3 years after the actual filing date of the application...not including (i) any time consumed by continued examination of the application requested by the application under section 132(b)...the term of the patent shall be extended 1 day for each day after the end of that 3-year period until the patent is issued.” 35 U.S.C. §154(b)(1)(B). The instant application was filed on June 27, 2003. Thus, the three-year anniversary of the filing date is June 27, 2006. According to the Issue Notification of October 7,

2009, the date of issuance will be October 27, 2009. Thus, the period of Office delay pursuant to 35 U.S.C. §154(b)(1)(B), calculated from June 27, 2006 to October 27, 2009, is 1,218 days.

3. Total Patent Office Delays

The patent term adjustment due to PTO delays is the sum of Office delays under 35 U.S.C. §154(b)(1)(A) and 35 U.S.C. §154(b)(1)(B). *See Wyeth v. Dudas*, 88 U.S.P.Q.2d 1538 (D.D.C 2008). However, “[t]o the extent that period of delay attributable to grounds specified in paragraph (1) overlap, the period of any adjustment granted under this subsection shall not exceed the actual number of days the issuance of the patent was delayed.” *Id.* at 1539, citing 35 U.S.C. §154(b)(2)(A). Overlap occurs “only if they occur on the same calendar day or days.” *Id.* at 1541.

As discussed above, the PTO delay under 35 U.S.C. § 154(b)(1)(A) occurred from August 27, 2004 to January 11, 2006, from December 20, 2007 to January 28, 2008, and from November 24, 2008 to November 26, 2008. The period of Office delay under 35 U.S.C. § 154(b)(1)(B) was between June 27, 2006 and October 27, 2009. In these periods, a total of 41 calendar days overlap: 39 days between December 20, 2007 and January 28, 2008, and 2 days between November 24, 2008 and November 26, 2008. Accordingly, the total patent term adjustment due to PTO delay is $543 + 1,218 - 41 = \underline{1,720\text{ days}}$.

4. Applicants' Delay under 37 C.F.R. §1.704

Applicants do not dispute the Office's determination of Applicants' delay of 300 days, as provided in the Patent Term Adjustment History obtained from PAIR.

A response to Office Action was filed on May 31, 2002 in reply to a Restriction Requirement mailed January 11, 2006. Thus, a delay of 50 days was assessed by the Office in the Determination for the filing of a reply after three months from the mailing date of an Office Action. *See* 37 C.F.R. § 1.704(b).

A response to Office Action was filed on February 15, 2007 in reply to a non-final Office Action mailed August 15, 2006, a delay of 92 days. *Id.*

A supplemental response to Office Action was filed on October 30, 2007, 71 days after the August 20, 2007 filing of a response to Office Action. Thus, a delay of 71 days was assessed by the Office for the filing of a supplemental reply. *See* 37 C.F.R. § 1.704(c)(8).

Finally, a response to Office Action was filed on July 24, 2008 in reply to a non-final Office Action mailed January 28, 2008, a delay of 87 days. See 37 C.F.R. § 1.704(b).

Accordingly, the total of Applicants' delay is $50 + 92 + 71 + 87 = \underline{300}$ days.

5. Total Patent Term Adjustment

In view of the above, the total patent term adjustment is the difference between total Office delays under 35 U.S.C. §154(b)(1)(A) and (B), and total Applicant delays, i.e. $1,720 - 300 = \underline{1,420}$ days.

B. Terminal Disclaimers

The Terminal Disclaimer filed July 24, 2008 in the above-captioned application has been withdrawn. No other Terminal Disclaimer has been filed in the above-captioned application. Therefore, as no Terminal Disclaimer exists in connection with the above-captioned application, the correct patent term adjustment is 1,420 days.

C. Conclusion

The fee of \$200.00, which is due for the submission of this paper under 37 C.F.R. §1.18(e), will be paid via EFS Web. If any additional fees are due, the Commissioner is authorized to charge them to Deposit Account No. 50-3013 (referencing 417451-999055).

Respectfully submitted,

Date: December 23, 2009


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